K003256

NOV - 8 2000

510(k) Summary
for
PcCR Digital Imaging Devices for X-Ray Systems

1. Date Summary Prepared

October 13, 2000

2. Submitter's Name and Address

Orex Computed Radiography Ltd.
Yoqneam "Star" Bldg.
Yoqneam, P.O. Box 465
NESHER 36603
ISRAEL

3. Contact Person

Dr. Raanan Aloni
Telephone: 011 972 4 959 1331
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4. Device Name

Trade/Proprietary Name: PcCR Digital Imaging Device for X-Ray Systems
Common Name: Accessory to Electrostatic X-ray imaging system
Classification Name: Accessory to Electrostatic X-ray imaging system

5. Predicate Devices

The legally marketed devices to which equivalence is being claimed are:

- Lumisys Lumiscan 135 Digital Imaging System (K980809)
- AGFA ADC Compact (K974597)
- Orex Computed Radiography Ltd. CD-Dent Dental Imaging System (K990049)

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6. DEVICE DESCRIPTION

The PcCR Digital Imaging Devices are essentially identical to the CD-Dent Digital Imaging Devices, which were cleared under 510(k) K990049 and are currently in commercial distribution, with the exception of a change in indications and other minor design modifications.

The PcCR Digital Imaging Devices for X-Ray Systems are filmless systems intended for digital radiography using a phosphor storage screen. As with the CD-Dent devices, the PcCR devices enable the clinician to scan or import images for display, review, or storage in a database. The PcCR device consists of reusable phosphor storage screens for recording radiographic images, an image reader/digitizer, and software for displaying, enhancing, and storing radiographs using a user-provided personal computer.

The minor differences between the proposed PcCR and the parent device, the CD-Dent, include the addition of several phoshor plate sizes to accommodate the new indications, an optical engine change for the convenience of the user and a computer interface change to a USB interface card and driver. The driver has easy software tools to interface with any PACS software package having the same standard CR specifications such as Fuji, AGFA, etc.

Other than the plate sizes and minor design changes described above, all of the other major components of the PcCR Digital Imaging Devices are identical to those described in K990049 for the CD-Dent System.

7. INTENDED USE

The PcCR Digital Imaging Devices for X-Ray Systems are intended for digital radiography using a phosphor storage screen for standard radiographic diagnostic images.

8. BASIS FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE

Orex Computed Radiography Ltd. bases the claim of equivalence to cited predicate devices upon similarities in intended use, technological characteristics, and operational characteristics. Bench testing and clinical validation demonstrate that the PcCR performs according to specifications.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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OREX Computed Radiography Ltd.
c/o Rosina Robinson
Senior Staff Consultant
Medical Device Consultants, Inc.
49 Plain Street
North Attleboro, MA 02760

Re: K003256
PcCR Digital Imaging Devices (PcCR 812, PcCR 1417)
Dated: October 16, 2000
Received: October 17, 2000
Regulatory class: II
21 CFR 892.1630/Procode: 90 MQB

Dear Ms. Robinson:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

510(k) Number (if known): K003256

Device Name: PcCR Digital Imaging Devices (PcCR812 and PcCR1417)

Indications For Use:

The PcCR Digital Imaging Device is intended for digital radiography using a phosphor storage screen for standard radiographic diagnostic images.

(PLEASE DO NOT WRITE BELOW THIS LINE CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Segram

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K003256

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)